

REMARKS

Claims 1, 3 to 13, 22, and 27 are in the application. Claims 2, 14 to 21 and 23 to 26 are cancelled.

Claims 1, 9, 10, 12, 22, 26 and 27 have been amended. Claim 1 has been amended to incorporate the limitations of Claim 2. Support for the amendments lie in the original claims as filed and the specification on page 4, lines 4 to 7; and page 5, lines 14 to 16.

Applicants thank the Examiner for the Interview of 14 November 2003 in this application. The amendments and submission of articles herein are in response to the discussion raised therein.

Rejection of Claims under 35 U.S.C. § 112

Claim 10 is rejected under 35 USC §112, second paragraph as being indefinite for the term "the sweet is a pastille". Applicants respectfully traverse this rejection.

The specification has been amended to incorporate the term "pastille", present in the originally filed claims into the list of suitable dosage forms for the compositions disclosed herein. No new matter is believed added. A pastille is an art recognized pharmaceutical dosage form. In support of this, please find enclosed a copy of the relevant page (page 1664) from Remington's Pharmaceutical Sciences, 18th Edition.

Claims 9 and 10 have been amended to more particularly point out and better define the invention. In view of these amendments, withdrawal of the rejection and reconsideration and allowance of the claims is respectfully requested.

Rejection of Claims under 35 U.S.C. § 103 (a).

Claims 1 to 13, 22, 26 and 27 are rejected under 35 USC §103(a) as being unpatentable over De Wille et al. (US 5,597,595) or Burkes et al. (US 5,335,837). Applicant respectfully traverses this rejection.

As previously noted, the skilled artisan has been unable to readily determine how to reduce tooth erosion in a solid or semi-solid composition for oral use. Applicant has determined that by requiring only the addition of calcium to an acidic composition in a particular molar ratio, and maintaining the pH of the effective composition that tooth erosion is reduced.

The concept of identifying a composition which is effective against tooth erosion by reference to calcium:acid molar ratio and their pH in solid or semi-solid compositions

is believed to be novel and inventive over the cited De Wille et al. and Burkes et al references.

Upon review of the working examples in the Burkes et al. '837 patent it is possible to calculate the molar ratio of calcium to acid in Examples 1, 3, 4, 5, 6, and 7. However, the pH of the resulting composition is not determined for all of these. Example 1 is stated to have a pH of 3.12; Example 3 a pH of 2.7; Example 4, a pH of 2.6; Example 5, a pH of 3.05; Example 6 appears to have a pH of the combination presented of 3.06; and according to calculations, the sweetener composition of Example 7 will provide a calcium to acid molar ratio above 0.8, hence outside of the claimed range herein.

The molar ratios of the composition of the Burkes et al. '837 patent are outside the claimed invention as amended herein. The lowest ratio which one can calculate in the Burkes et al. patent is in Example 5, which has a ratio of about 0.63 and for Examples 1 and 4 a ratio of 0.65 is determined. However, the second limitation of Claim 1, that the effective pH of the composition be from 3.5 to 4.5 is not met by these Examples.

The Burkes et al. Examples 6 and 7 also do not provide any teaching or suggestions towards the present invention. In Example 6 (first stage) the same composition as that of example 3 is used. The composition of Example 3 is stated to have a pH of 2.7, which pH is outside the range as claimed in claim 1 herein. The Burkes et al. Example 6 composition is also made up into a punch which has a resulting pH of 3.06, again which is outside of the claimed range of 3.5 to 4.5. The mole ratio of the punch cannot be calculated since we do not know the composition of the "citrus punch".

In Example 7 (first stage) the pH cannot be determined but the composition has a mole ratio 0.83 which is outside the range of claim 1. In the second stage, the first stage composition is blended with a strawberry mix product to make a strawberry drink. The composition contains no fruit acids, therefore adding more calcium will only tend to shift the mole ratio higher than the claimed range.

It should also be noted that the '837 patent is not consistent in its teachings of pH of the resulting compositions. The specification provides a basic disclosure of a suitable range, see column 9, lines 39 to 44, to be "less than or equal to about 3.8. *Preferably the pH is less than or equal to about 3.4, and more preferably less than or equal to about 3.2.* Typically, the pH will range from about 2.5 to about 3.8". However, in column 12, lines 32 to 34 the skilled artisan is taught that preferably the pH the dry powder composition to *preferably* have a pH of about 3.7.

In the 5,597,595 ('95) De Wille et al. patent the embodiments of the preparations contained in Tables 18, 19, 20 and 21 provide for a composition having a molar ratio of 0.68 and in Example 7, Table 25 a molar ratio of 0.74. There is insufficient details provided to either calculate the calcium:acid molar ratio of the other examples, or a pH is not provided for those compositions which one can calculate a ratio for.

Neither the Burkes et al. nor the De Willie et al. patents direct the skilled artisan to a balancing of these factors (calculation of the calcium:acid molar ratio maintenance of the final pH of the composition) for the end use of these compositions. There is no recognition that such a combination of factors would be inhibit or reduce of tooth erosion, but instead direct themselves to dietary supplementation compositions.

The references therefore require at least two modifications of the compositions to meet the limitations of the claims herein. In some instances, both the molar ratio and the pH must be modified, in some just on of the factors. There is, however, no motivation in these references to direct the skilled artisan to optimize these factors, either to improve the stability of CCM, or for Vitamin D supplementation. Since the Burkes et al. and the De Willie et al. applications relate to calcium supplementation, if the skilled addressee were to set out to optimize the compositions disclosed therein (as asserted by the Examiner), he would not arrive at compositions falling within the scope of the claimed invention. The skilled artisan's objective would be to add more calcium. By adding more calcium the mole ratio will be higher than the ratios already calculated from the Examples in Burkes et al. and De Wille et al., e.g. higher than the 0.83 of Example 7 in Burkes et al. and more distant from the claimed range of 0.3 to 0.6.

The absolute amount of calcium present in a composition prepared according to the invention herein is not critical. It is the molar ratio of calcium to total acids. It is this recognition, *the molar ratio of calcium to total acid* in a solid or semi-solid composition, which is the heretofore an unrecognized invention to reduce tooth erosion.


Therefore, neither the Burkes et al. or the De Willie et al. references teaches or motivates the skilled artisan to make the necessary changes to achieve a composition as claimed.

In view of these remarks Applicant respectfully requests that the rejection to the claims under 35 USC §103 be withdrawn.

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stephen Venetianer", written over the printed name.

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